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10/032,376	12/21/2001	Stephen Quirk	1443.008US1	5459

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. BOX 2938  
MINNEAPOLIS, MN 55402-0938

EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/032,376

Applicant(s)

QUIRK, STEPHEN

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 14, 15 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 2-13, 16-26, and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 14, 15 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/4/05, 1/28/03
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

RD

**DETAILED ACTION**

Claims 1-28 are pending. Claims 1, 14-15, and 27 are drawn to the elected invention and examined on the merits. It is noted, for clarification, as Applicant acknowledged, that the withdrawn claim are claims 2-13, 16-26, and 28. Claims 2-13, 16-26, and 28 are withdrawn from consideration. In response to this action, Applicant is asked to cancel the withdrawn claims (see attached Interview Summary, approved by Applicant). The IDS submitted 1/28/03 has been considered and a signed copy of the Form 1449 is being sent herewith.

***Claim Rejections - 35 USC § 101***

The rejection of claim 1 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is maintained for the reasons of record. As drafted, the claims read upon a product of nature (i.e. a non-isolated peptide). It is suggested that Applicant insert the phrase "an isolated" or the like before the term "peptide" in claims 1, 14-15, and 27, in order to show the hand of man and thus statutory subject matter (see attached Interview Summary, approved by Applicant).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1, as drawn to SEQ ID NO: 8, is rejected under 35 U.S.C. 102(b) as being anticipated by Seiki et al. (US 6,184,022 B1). Seike et al. teach a 708 residue peptide (SEQ ID NO: 16) with 100% homology (residues 74-120) to Applicant's elected SEQ ID NO: 8. Seike et al. also teach a 468 residue peptide (SEQ ID NO: 13) with 100% homology (residues 66-120) to Applicant's elected SEQ ID NO: 10.

Claim 1, as drawn to SEQ ID NO: 8 or 9, is rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (US 6,812,339 B1). Venter et al. teach a 713 residue peptide (SEQ ID NO: 10629), containing Applicant's SEQ ID NO: 8. Venter et al. also teach a 491 residue peptide (SEQ ID NO: 10875) with 100% homology (residues 89-142) containing Applicant's SEQ ID NO: 9.

Claims 1, 14-15, and 27, as drawn to SEQ ID NO: 10, is rejected under 35 U.S.C. 102(b) as being anticipated by Hu (Statutory Invention Registration US H1973 H). Hu teach a 444 residue peptide (SEQ ID NO: 2), containing Applicant's SEQ ID NO: 10. Hu also teach a 491 residue peptide (SEQ ID NO: 10875) with 100% homology (residues 89-142) containing Applicant's SEQ ID NO: 10, in a composition with a carrier (see i.e. claim 30, col. 23-24) and for use in products (i.e. dressing), as an inhibitor against other peptides, for the treatment of wounds (see i.e. col. 23-24).

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The rejection of claims 1 and 14-15, as drawn to SEQ ID NO: 8, under 35 U.S.C. 102(e) as being anticipated by Falduto et al. (US 6,399,371 B1), is maintained for the reasons of record. As stated in the previous action, Applicant's invention is drawn in part to a peptide/products using elected SEQ ID NO: 8. Falduto et al. teach a 707 residue peptide (SEQ ID NO: 20) with 100% homology (residues 74-120) to Applicant's elected SEQ ID NO: 8. Additionally, Falduto et al. teach the use of peptides (i.e. SEQ ID NO: 8) which may act as inhibitors (i.e. to the full-length peptide) in a composition with a carrier (see col. 27, lines 14-37).

The rejection of claims 1, 14-15, and 27, as drawn to SEQ ID NO: 9, under 35 U.S.C. 102(e) as being anticipated by Dack et al. (2003/0199440 A1). Applicant's invention is drawn in part to a peptide/products using elected SEQ ID NO: 9. Dack et al. teach a 469 residue peptide (SEQ ID NO: 23) with 100% homology (residues 67-120) to Applicant's elected SEQ ID NO: 9, in a composition with a carrier (see i.e. abstract) and in products (i.e. dressing), as an inhibitor against other peptides, for the treatment of wounds (see i.e. abstract, para 0154, claim 1, and claims 6, 11, 12, 16, 17, 20, 23-25).

Claims 1, 14-15, and 27, as drawn to SEQ ID NO: 10, are rejected under 35 U.S.C. 102(e) as being anticipated by Dack et al. (2003/0199440 A1). Applicant's invention is drawn in part to a peptide/products using elected SEQ ID NO: 10. Dack et al. teach a 467 residue peptide (SEQ ID NO: 31) with 100% homology (residues 66-120) to Applicant's elected SEQ ID NO: 10 in a composition with a carrier (see i.e. abstract) and in products (i.e. dressing), as an inhibitor against other peptides, for the treatment of wounds (see i.e. abstract, para 0154, claim 1, and claims 6, 11, 12, 16, 17, 20, 23-25).

As to Applicant's argument to each of the references, Applicant has argued that each reference teaches the full-length sequence, and thus cannot teach a peptide "wherein the peptide can inhibit matrix metalloproteinase", because the full-length cannot inhibit itself. This is not found persuasive, as evidenced for example in the 1<sup>st</sup> rejection of SEQ ID NO: 8, under Falduto et al., teaching a 707 amino acid peptide containing SEQ ID NO: 8 (including peptide inhibitors of the peptides within the invention, in a composition with a carrier (see col. 27, lines 14-37). Seiki et al., among other references in the art, is added as a reference also teaching a peptide containing SEQ ID NO: 8, which is in a 708 amino acid length peptide (Applicant may also be directed to i.e. Venter et al., US 6,812,339 B1 to a 713 residue peptide of SEQ ID NO: 10629, containing Applicant's SEQ ID NO: 8). Thus, Falduto et al. (and the other references) cannot be deemed to teach the full length peptide, absent evidence to the contrary. Therefore, the Falduto et al. reference is deemed to anticipate the claims in light of the "comprising" transitional phrase, and the peptide inherently contains the functional language "wherein the peptide can inhibit matrix metalloproteinase".

Again, in order to overcome the rejections above, it is suggested that Applicant amend claims 1, 14-15, and 27, by deleting the open transition phrase "comprising" and inserting "consisting of".

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-15, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falduto et al. (US 6,399,371 B1) in view of either Dack et al. (2003/0199440 A1) or Hu (Statutory Invention Registration US H1973 H).

Falduto et al. is discussed above. Falduto et al. teach the use of peptides (i.e. SEQ ID NO: 8) which may act as inhibitors (i.e. to the full-length peptide) in a composition with a carrier (see col. 27, lines 14-37), but does not expressly teach the use of SEQ ID NO: 8 to treat wounds, i.e. in wound dressing.

Dack et al. and Hu et al. teach SEQ ID NOS: 9 and 10 in compositions with carriers, as well as in the treatment of wounds, and products containing the same.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the matrix metalloproteinase of SEQ ID NO: 8 in wound products (i.e. dressings) in Falduto et al., since Dack et al. and Hu each teach the advantageous use of related matrix metalloproteinases in wound treatment and products containing the same, and in light of Falduto et al.'s use of related matrix metalloproteinases such as SEQ ID NO: 8 in compositions with carriers.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

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Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

### ***Double Patenting***

The provisional rejection of claims 1, 14-15, and 27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-73 (i.e. claims 1 and 63) of copending Application No. 10/219,561 (Quirk et al., 2003/0166567 A1) and claims 1-40 (i.e. claims 18 and 23) of copending Application No. 10/219,329 (Quirk et al., 2003/0096757 A1), is maintained for the reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because 10/219,561 and 10/219,329 claims the same peptides (SEQ ID NOS: 8-10, among the various other peptides claimed) and compositions/products using the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

As Applicant requested, this rejection is held in abeyance, but maintained, until there is an indication of allowable subject matter in the cited Applications.

It is noted that the claims are rejected as indicated, over all claims, under both references, and that the parenthetical reference to “i.e.” to certain claims was merely “by example”.



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*Conclusion*

No claims are allowed.

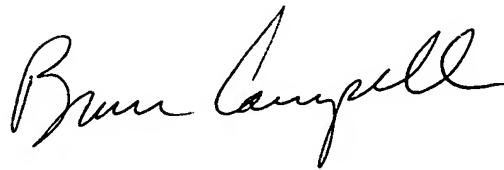
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 05/25/2005

A handwritten signature in black ink, appearing to read "Bruce Campell", with a stylized, cursive script.

BRUCE R. CAMPELL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600